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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

YU, MELANIE J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/735,153

Applicant(s)

BALLERSTADT ET AL.

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31, 71-80 and 102-117 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-31, 71-80 and 102-117 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/29/8/9/1/28.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments filed 10 February 2005 and 01 March 2005 have been entered. Claims 1-31, 71-80 and 102-117 are pending. Claims 32-70 and 81-101 have been canceled.

Specification

2. The use of the trademark Alexa647, LD800 and QSY21 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

3. Claims 4 and 5 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 2 and 3. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-31, 71-80 and 102-117 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1, 13, 14, 29, 71, 74, 75, 78-80, 102 and 115 recite the phrase "capable of converting radiation", which is vague because it is unclear what is meant by converting radiation. It is unclear as to whether a radiation is emitted at a wavelength different than that of the first radiation wavelength or whether the component is detected with a wavelength other than that of the first wavelength. Furthermore, it is unclear how the conversion is dependent or independent on the concentration of the analyte within the housing. It is unclear if the conversion affects an increase or decrease in the at least one different wavelength.

Regarding claims 3 and 16, the claims recite the phrase "in close proximity", which is unclear because it is vague as to what distance encompasses a close proximity.

With respect to claim 12, the phrase "analyte-specific analyte binding ligand" is unclear because it is vague as to whether this is the same analyte-specific binding ligand as claim 1.

5. Claims 1, 13, 14, 18, 29, 71, 75, 78, 79 and 102 recite the limitation "the efficiency" in the claim. Claims 72, 78, 79 and 80 recite the limitation "the intensity" in the claim. There is insufficient antecedent basis for these limitations in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 4, 6-8, 11, 12, 15-21, 23, 24, 27, 28, 31, 71, 72, 77, 102-107, 109-110, 113-114 and 117 are rejected under 35 U.S.C. 102(b) as being anticipated by Chick et al. (US 6,040,194).

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With respect to claims 1, 2, 4, 6, 7, 11, 15, 71 Chick et al. teach an analyte sensing device for sensing a concentration of analyte in a fluid and capable of being implanted within subcutaneous tissue of an animal body (col. 17, lines 39-43), comprising: a housing including a hollow dialysis fiber (col. 12, lines 9-13; col. 13, line 66-col. 14, line 3) and the housing comprising a semipermeable membrane (col. 5, lines 57-58); an analyte sensing component disposed within the housing and including: a first radiation converting component that is capable of converting radiation of a first wavelength to radiation having at least one different wavelength, wherein the efficiency of conversion is dependent on the concentration of analyte within the housing (converting component is the donor component; col. 3, lines 9-13; col. 5, lines 57-67); an analyte specific binding ligand being lectin (col. 2, line 66-col. 3, line 2; col. 10, line 15) in close proximity to a radiation absorbing component (col. 5, lines 63-65); and a macroporous matrix wherein the analyte-specific binding ligand is attached to the surface of the macroporous matrix (col. 5, lines 57-67); a radiation providing unit to provide radiation at the first wavelength (col. 16, lines 32-34; col. 17, lines 22-25); and a radiation detecting unit to detect the radiation of at least one different wavelength and output data which is representative of the intensity of the radiation of the at least one different wavelength (col. 16, lines 35-36).

Regarding claim 8, Chick et al. teach an analyte sensing component further including a radiation absorbing component in close proximity to the analyte-specific binding ligand (acceptor component is an absorbing component; col. 3, lines 9-13; col. 5, lines 57-67).

With respect to claim 12 and 102, Chick et al. teach an analyte sensing component further comprising an analyte-analogue capable of being bound by an analyte-specific binding ligand (ligand labeled with acceptor and donor; col. 5, lines 57-67).

With respect to claims 16-21, 23, 24, 103-107 and 109-110, Chick et al. teach an analyte sensing component further comprising: an analyte analogue (analogue, col. 5, lines 57-67) of dextran (col. 14, lines 55-57), a glycosylated protein (col. 10, lines 13-17) or a chain of glucose residues (col. 10, line 62); a radiation absorbing component in close proximity to the analyte specific binding ligand (first radiation absorbing component attached to analogue; col. 5, lines 57-67); and wherein the first radiation converting component is attached to the analyte analogue and the analyte specific binding ligand is capable of binding to the analyte and the analyte-analogue (col. 5, lines 57-67). Chick et al. further teach a housing comprising a semi-permeable membrane, which allows analyte to move into or out of the housing, but does not allow analyte-sensing components to move out of the housing (col. 5, lines 57-58). Chick et al. also teach the efficiency of conversion of radiation at a first wavelength to radiation having at least one different wavelength by the first radiation converting component is decreased when the analyte-analogue is bound by the analyte specific binding ligand (the radius, R, decreases when analyte-analogue is bound to analyte ligand, and therefore the efficiency of conversion is decreased; col. 8, lines 48-65). Chick et al. teach the ligand being a lectin (col. 10, line 15) of Concanavalin A (col. 8, lines 50-54).

With respect to claims 27, 28, 31, 113-114 and 117, Chick et al. teach a radiation absorbing component covalently bound to the analyte-specific binding ligand (acceptor component; col. 10, lines 60-63), and wherein the radiation absorbing component (acceptor component) is attached to the surface of the macroporous matrix (col. 5, lines 57-67). Chick et al. also teaches the analyte being glucose (col. 9, lines 50-54).

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Regarding claims 72 and 77, Chick et al. teach an analysis unit coupled to the radiation detecting unit to determine the concentration of analyte within the housing (col. 14, lines 6-11) and the radiation providing unit disposed adjacent to the housing (radiation providing unit is provided transdermally which is adjacent to the sensing system; col. 16, lines 32-36).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US 6,040,194) in view of Komives et al. (US 5,143,066).

Chick et al., as applied to claim 1, teach an analyte sensing device for sensing a concentration of analyte in a fluid comprising a semi-permeable membrane, but fail to teach the membrane comprising a cellulose acetate material.

Komives et al. teach a semi-permeable membrane comprised of a cellulose acetate material (col. 6, lines 4-9) in order to provide an ultra filtration dialysis membrane.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Chick et al., a cellulose acetate semi-permeable membrane as taught by Komives et al., in order to provide greater excitation signals and simultaneously capture a greater percentage of emitted light from a molecule to be analyzed.

8. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US 6,040,194) in view of Jordan (US 4,450,104).

Chick et al., as applied to claims 1, 23, 24 and 31, teach an analyte sensing device for sensing a concentration of analyte in a fluid with an analyte being glucose and the ligand including a lectin of Concanavalin A, but fail to teach the matrix comprising agarose beads.

Jordan teaches a macroporous matrix including agarose beads comprising lectin (col. 3, lines 21-31), in order to determine ligand binding on the lectin-agarose beads.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Chick et al., a matrix comprising agarose beads as taught by Jordan, in order to provide immobilized lectin ligands which bind rapidly, reversibly and are of high affinity.

9. Claims 13, 14, 29, 78-80 and 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US 6,040,194) in view of Mathies et al. (US 5,654,419).

Chick et al., as applied to claims 1, 71 and 102, teach an analyte sensing device for sensing a concentration of analyte in a fluid with a first radiation converting component, but fail to teach a second radiation converting component.

Mathies et al. teach a first and second radiation converting component, wherein the second radiation converting component is capable of converting radiation of a second

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wavelength to at least one different wavelength wherein the efficiency of conversion is dependent on (plurality of donor-acceptor pairs are used with different energy transfer and are detectably different; col. 1, line 63-col. 2, line 5; col. 3, lines 5-20) or independent of (col. 4, lines 16-22) the concentration of the analyte within the housing, in order to provide separation systems involving separation of a plurality of components.

Therefore it would have been obvious to one having ordinary skill in the art to include in the device of Chick et al., a second radiation converting component as taught by Mathies et al., in order to provide different donor-acceptor pairs for the multiplexing of samples and to determine a plurality of components.

Mathies et al. also teach an analysis unit using a difference in intensities of radiation detected by the radiation detecting unit due to at least one wavelength of the first radiation converting component relative to at least one wavelength of a second radiation converting component (wavelengths absorption maxima are within 20 nm of each other and the emitting fluorophores emit distinctive and detectable different light; col. 3, lines 5-20).

10. Claims 22, 26, 73-75, 108 and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US 6,040,194) in view of Djaballah et al. (US 2003/0059811).

Chick et al., as applied to claims 1, 16, 71 and 102, teach a device comprising a radiation converting component and a radiation absorbing component, but fail to teach the specific radiation converting and absorbing components.

Djaballah et al. teach a radiation converting component being Alexa647 (par. 0113) and a radiation absorbing component being QSY21 (par. 0115), in order to absorb light and transfer excitation energy causing fluorescence.

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Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Chick et al., radiation absorbing and converting components as taught by Djaballah et al., in order to provide more sensitive detection methods that can be configured for high throughput assays for ligands.

Regarding claims 73-75, Djaballah et al. teach a radiation detecting unit including a plurality of radiation detecting devices wherein each device is capable of detecting a wavelength-specific portion of radiation (par. 0254). Djaballah et al. also teach a first radiation converting component capable of converting radiation of the first wavelength to radiation having a plurality of wavelengths wherein the efficiency of conversion is dependent on the concentration of the analyte inside the housing; and the radiation detecting unit including a plurality of radiation detecting devices wherein each device is capable of detecting radiation within at least one of the plurality of wavelengths (par. 0254).

11. Claim 25 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US 6,040,194) in view of Cosma (US 6,150,123).

Chick et al., as applied to claims 1, 16, 23, 102 and 109, teach a device comprising a binding ligand of a lectin, but fail to teach the lectin being *Lens culinaris* lectin.

Cosma teaches *Lens culinaris* lectin (col. 6, lines 51-55) in order to bind α -D-glucose and α -D-mannose.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Chick et al., a ligand of *Lens culinaris* lectin to bind glucose as taught by Cosma, in order to provide a ligand that specifically binds glucose and retains its binding capacity in the presence of non-ionic detergents.

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12. Claim 30 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US 6,040,194) in view of Mathies et al. (US 5,654,419) further in view of Lakowicz et al. (US 2003/0228682):

Chick et al. in view of Mathies et al., as applied claim 29 and 115, teach a device comprising a second radiation converting component, wherein the component can be a rhodamine dye (Mathies et al., col. 4, lines 41-45).

Lakowicz et al. teach a dye of rhodamine 800 (par. 0108), which is the same as LD800 (see US 5,610,932; col. 12, lines 66-67), in order to provide a fluorophore that emits electromagnetic energy at a certain wavelength.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Chick et al. in view of Mathies et al., a rhodamine 800 dye as the second radiation converting component as taught by Lakowicz et al., in order to increase the radiative decay rate of weakly fluorescing species.

13. Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US 6,040,194) in view of Djaballah et al. (US 2003/0059811) further in view of Komives et al. (US 5,143,066).

Chick et al. in view of Djaballah et al., as applied to claims 75, teach an analyte sensing system comprising a first radiation converting component and a radiation detecting unit, but fail to teach the detection unit comprising one or more photodiode detectors.

Komives et al. teach a radiation detecting unit comprising a photodiode detector (col. 9, lines 24-25), in order to sense fluorescent light.

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Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Chick et al. in view of Djaballah et al., a photodiode detector as taught by Komives et al., in order to provide increased sensitivity for detecting concentration of analyte and shorter response time.

Conclusion

No claims are allowed.

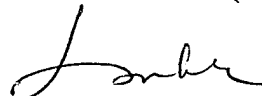
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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